TARRES OF LIBER

DEPARTMENT OF THE AIR FORCE

OFFICE OF THE CHIEF OF STAFF WASHINGTON, DC

MEMORANDUM FOR ALMAJCOM/CV

SUBJECT: Force Protection: Anthrax Vaccine Implementation Program (AVIP)

Recent negative press, misinformation, and poor communication have created new challenges for AVIP execution. We must act now to enhance communication on AVIP and to protect our people from the real and lethal threat posed by anthrax.

On 9 Jul 99, we held a HQ USAF Environment, Safety and Occupational Health Committee (ESOHC) meeting. During the meeting, ESOHC members reviewed and endorsed a plan to implement an AVIP leader's training initiative at all MAJCOMs and installations. The meeting minutes (Atch), including the plan and associated AVIP information, are provided for your action.

We request you call a special meeting of your MAJCOM ESOHC, or Environmental Protection Committee (EPC) and Air Force Occupational Safety and Health (AFOSH) Council, to begin implementing the plan we endorsed on 9 Jul 99. We recommend your installations take similar action.

The leader's training initiative will prepare commanders to communicate more effectively with their people on the anthrax threat and the vaccine. The resulting enhancement of direct commander involvement in the AVIP will help to streamline program execution, and, ultimately, protect our forces. Through your leadership and that of commanders throughout the Air Force, we will protect our most valuable asset, Air Force personnel, from the anthrax threat.

THOMAS W. L. MCCALL, JR. Deputy Assistant Secretary of the Air Force (Environment, Safety and Occupational Health)

DAVID L. VESELY Lieutenant General, USAF Assistant Vice Chief of Staff

Attachment:

HQ USAF ESOHC 9 Jul 99 Meeting Minutes w/Atch

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SAF/LL

SAF/IG

SAF/PA

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SAF/GCN

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HQ USAF/ILS

HQ USAF/XOO

HQ USAF/DPP

HQ ACC/CE/JA/LG/SE/SG/DP/FM

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HQ PACAF/CE/JA/LG/SE/SG/DP/FM

HQ AFSOC/CE/JA/LG/SE/SG/DP/FM

HQ USAFA/CE/JA/LG/SE/SG/DP/FM

HQ AFCEE/CC

HQ AFCESA/CC

HQ AFIT/CE

HQ AFIA/MIE

NGB/CF

HQ AFBCA/DR

11 WG/CE/JA/LG/SE/SG/DP/FM

¹ Distribution of courtesy copies will be made electronically. Please contact Maj John Coho, DSN 223-9534, <u>John.Coho@pentagon.af.mil</u>, if you experience difficulties receiving the minutes w/Atch.

Minutes of the 9 Jul 99 Air Force Environment, Safety and Occupational Health Committee (ESOHC) Meeting

The AF ESOHC met 9 Jul 99. Lt Gen Roadman, the Air Force Surgeon General (AF/SG) and Mr. McCall (SAF/MIQ) co-chaired the meeting. The focus of the meeting was Force Protection -- specifically, the Anthrax Vaccine Implementation Program (AVIP). Individuals attending from offices with required membership were as follows:

HQ USAF/IL/ILE	Mr. Aimone, SES	SAF/GC	Mr. Sheuerman	
HQ USAF/ILV	Lt Col Borgman	HQ USAF/SG	Col Sprester	
HQ USAF/ILM	Col Leonard	HQ USAF/RE	BGen Clem	
HQ USAF/IG	Col Schaule	HQ USAF/XP	MGen Kelly	
HQ USAF/SE	Mr. Burks	SAF/LL	Col Anderson	
NGB/CF	BGen McKinley	HQ USAF/HC	MGen Dendinger	
SAF/IA	BGen DeWolf	HQ USAF/JA	Mr. Wilder, SES	
SAF/AQR	Col Williams	SAF/FM	Col Jones	
SAF/AQC	Col Kringer	SAF/FMC	Mr. Kammerer, SES	
HQ USAF/DPF	MGen Pamerleau	SAF/PA	Col Tyrrell	
HQ USAF/DPR	BGen Regni	AFBCA/DR	Ms. Frank	
HQ USAF/SC	Col Whitechurch	HQ USAF/XO	BGen Dordal	

Opening Remarks

Mr. McCall opened with a welcome to all. He noted that Lt Gen Vesely (HQ USAF/CVA) could not be present because he was called away to represent the CSAF, but that he asked Mr. McCall to deliver a message to the ESOHC membership.

In his message, Lt Gen Vesely expressed his strong commitment to the AVIP as a crucial Force Protection requirement and a fundamental commander's responsibility. Referring to the recent negative press and misinformation regarding the AVIP, Lt Gen Vesely called for ESOHC action to educate Air Force personnel, including commanders, on three key points regarding AVIP:

- First, force protection: anthrax is a real, and lethal, threat from which Air Force personnel must be protected if we are to survive and operate effectively in a biological warfare environment.
- Second, force protection is a commanders' responsibility.
- Third, timely communication of factual, accurate information is essential to success of the AVIP.

Following Mr. McCall's delivery of Lt Gen Vesely's message, Lt Gen Roadman addressed the ESOHC with his opening remarks. He started by briefly polling the attendees on the history of infectious diseases (e.g., polio, smallpox, and typhoid) in their families. Aside from a single positive response from MGen Dendinger (AF/HC), none of the 33 attendees had any recollection of such diseases affecting their family. The lack of positive response underscored Lt Gen Roadman's initial point: as a society, we're largely unfamiliar with infectious disease and the associated symptoms. As a result, we tend to fear the immunization against the disease more than the disease itself. In the case of anthrax, the fear of immunization is further compounded by a lack of trust in

government related to the "Gulf War Syndrome," Agent Orange, and other government activities alleged to have impacted the health of Service members.

Lt Gen Roadman acknowledged that fear of immunization and trust of government are "problems," but they can, and must, be overcome if we're to protect our forces against the anthrax threat. He pointed out that anthrax is a uniformly fatal disease and our "number one" biological warfare threat. To illustrate the lethality of the threat, he cited the fact that Iraq is known to have had weaponized anthrax in-place during the Gulf War. He then described a likely scenario following an anthrax attack on a non-immunized force: "Initially, we'd see a big run of "flu," and most people would appear to recover. But after 2 or 3 days, nearly 99% of our people would be dead." Lt Gen Roadman added that while human testing of vaccine effectiveness is impractical, tests on monkeys have shown the vaccine is highly effective -- 95% of immunized monkeys survived a dose of anthrax equal to 50-times the "lethal dose."

Emphasizing his personal and professional confidence in the safety and effectiveness of the vaccine and the uniformly lethal threat posed by anthrax, Lt Gen Roadman told the ESOHC that failure to immunize Air Force personnel would constitute medical malpractice and leadership negligence. Finally, he closed by clarifying the AVIP is not a "medical" issue; rather, it is a Force Protection issue. As such, AVIP is a fundamental responsibility of the line leadership of the Air Force. He called on the ESOHC to take action to educate commanders and provide them the training aids and information they need to communicate effectively with their people on the anthrax threat and the AVIP.

Following Lt Gen Roadman's remarks, BGen Clem (AF/RE) interjected a comment on behalf of Gen Sherrard, stating that the Air Force Reserve is on-board, and Air Force policy on AVIP will be upheld in the Reserves. The ESOHC then watched a video (Atch 1) of Lt Gen Roadman speaking with personnel at Dover AFB about the AVIP. The video set the stage for a briefing by AF/SGO and the Air Force Anthrax IPT on the status of the AVIP.

Force Health Protection: Anthrax Vaccine Implementation Program

Col Crowder (AFMOA/SGOP) opened by explaining the purpose of the briefing was to obtain ESOHC endorsement of a plan to enhance communication on AVIP and direct commander involvement in support of the AVIP. Direct leadership involvement is seen as a crucial component of a credible and effective AVIP education and training program.

Col Crowder provided a quick synopsis of the status of the AVIP, showing that over 300,000 personnel across DoD have received their first immunization, including more than 83,000 Air Force personnel as of 30 Jun 99.

Following his assessment of Air Force success to date with implementation of the vaccine, Col Crowder discussed the threat posed by anthrax as a biological weapon. 10 countries have weaponized anthrax. Because it is easy and inexpensive to manufacture and disperse, the threat posed by anthrax is very real. So real, in fact, that Lt Gen Roadman stated his belief that use of anthrax in an attack on US military personnel is not a question of "if," but "when." Clearly, anthrax is our "number one" biological warfare threat.

The chairperson of the Air Force Anthrax IPT, Lt Col Rossi, followed Col Crowder. Lt Col Rossi described the Anthrax IPT as the cross-functional team established by AF/CV to oversee implementation of the AVIP, improve education and training, and review policies, processes, operations, morale and discipline as they pertain to the AVIP. She discussed the issues and

concerns facing Air Force personnel, ranging from misinformation and non-scientific journalism to "grounding" of rated personnel as a result of side effects from the immunization.

During Lt Col Rossi's presentation, Mr. McCall brought up the issue of "squalene" in the anthrax vaccine. Lt Gen Roadman responded to Mr. McCall explaining that squalene is a chemical closely related to cholesterol, and it is already present in our bodies. Further, squalene is neither a component nor a contaminant in the anthrax vaccine, and it never has been. Finally, Lt Gen Roadman briefly referred to the Tulane University study of "anti-squalene antibodies," and made a clear statement that if such antibodies exist, they aren't a result of the anthrax vaccine.

The IPT's bottom line assessment of the AVIP is that there is a clear need for enhanced information, education, and leadership involvement if the AVIP is to succeed in the present "information warfare" environment. She called for development and dissemination of improved information on AVIP using all available conduits, such as the internet and commander's calls. Lt Col Rossi emphasized the need to educate Air Force leaders on AVIP and risk communication so they are better prepared to deliver a clear, concise and fully responsive message on AVIP to their personnel.

Recommendation

To accomplish these tasks, she recommended the ESOHC endorse the following plan:

- 1. HQ USAF ESOHC request AVIP-focused ESOHC/EPC-AFOSH Council meetings at all levels of the Air Force.
- 2. HQ USAF ESOHC distribute across the Air Force the HQ USAF ESOHC minutes, the AVIP Leader's Brief, the AF News video from Dover AFB, and web-site information to provide a foundation of consistent and accurate information on which commanders may build effective AVIP communication efforts.
 - 3. MAJCOMs and installations implement an AVIP leader's training initiative.

Discussion

Following the AVIP briefing and the IPT's recommendation, Mr. McCall opened the floor for discussion. BGen Dordal (AF/XOO) opened the discussion with a question on the alleged adverse reactions to the vaccine in the Michigan Air National Guard. Lt Gen Roadman responded that various pre-existing conditions were the likely cause of these alleged reactions to the vaccine. He was clearly convinced that there was not a cause and effect relationship between the reactions and the vaccine.

The next question came from MGen Kelly (AF/XP). He asked why there appeared to be a range of possible responses to incidents of vaccine refusal, citing the apparent ability of reserve component personnel to refuse the vaccine and resign without retribution. BGen McKinley (NGB/CF) responded that in the Air National Guard, personnel are given the opportunity to resign only if their service commitments are fulfilled; otherwise, Guard personnel are obligated to take the vaccine or face disciplinary action.

Lt Gen Roadman interjected an important point regarding the magnitude of the "refusal problem." He pointed out that with over 300,000 immunizations already given across DoD, only 220 personnel have refused. Regardless of the amount of media coverage the vaccine refusals have generated, such incidents are highly uncommon. The vast majority of military personnel accept the vaccine as a routine part of their military duty.

Lt Gen Roadman once again emphasized the need for line commanders to engage directly with their personnel in the AVIP education and training process. Mr. Aimone (AF/ILE) concurred with Lt Gen Roadman, and stated that a meeting of commanders is a very effective forum in which to address "command issues," such as AVIP, as opposed to calling a "team of experts." His comment provided clear support for the IPT's recommendation that leaders at all levels of the Air Force convene ESOHC/EPC-AFOSH Council meetings to address AVIP.

BGen McKinley (NGB/CF) provided further support for leadership engagement and improved communication, as he noted his superiors, Lt Gen Davis & MGen Weaver, were concerned that vaccine refusals in the Connecticut Air National Guard resulted from a lack of information and communication. He concluded by stating that the ANG is "on-board" and plans to complete the AVIP for those participating in AEF rotations.

BGen Dordal (AF/XO) agreed that communication on AVIP is very important to the program's success, but he cautioned the ESOHC membership not to conclude that field commanders have been "non-players" in the AVIP to date. He emphasized that communication is a two-way street involving a speaker and a listener. To illustrate his point, he cited the relative ease of implementing the AVIP in Korea, a situation in which Air Force personnel are closely tuned-in and "listening" to the AVIP message, because they are so close to the reality, and the lethality, of the anthrax threat.

Referring to the information the ESOHC would be distributing to the field in support of AVIP, MGen Pamerleau (AF/DPF) recommended that emergency essential civilian personnel requirements for the AVIP be included in the package. Mr. Burks (AF/SE) followed with a similar remark, calling for AVIP guidance for contractor personnel.

The final comment during discussion came from MGen Dendinger (AF/HC). He asked for information on medical conditions that would prevent personnel from receiving the anthrax vaccine. Col Crowder responded that if a person has a known allergy to the vaccine, a compromised immune system, or is pregnant, the person would not be required to take the vaccine. Lt Gen Roadman added that although there is no known medical reason to withhold the vaccine from pregnant women, the medical community generally avoids administering any type of medication during pregnancy. MGen Dendinger closed with brief mention that some personnel may claim religious belief as a basis for refusing the vaccine.

Decision

As the meeting closed, Mr. McCall asked the membership of the ESOHC if there were any objections to implementing the plan proposed by the IPT. No objections were voiced, so Mr. McCall concluded with a brief statement that the plan to engage Air Force leaders through ESOHC/EPC-AFOSH Council channels would move forward as proposed by the Air Force Anthrax IPT.

Attachments:

- 1. ESOHC Read-ahead Materials
- 2. AVIP Leader's Brief
- 3. Video AF/SG Speaking on Anthrax (See local PAO for videotape)
- 4. Web Site Information



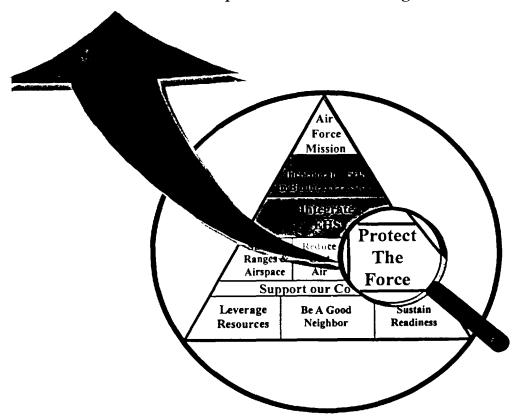
United States Air Force

Environment, Safety and

Occupational Health Committee

1999. The Year of "Operation alizing" ESOH

9July99 FORCE HEALTH PROTECTION A ii tli rax Vaccination Imp lemen tation Pro grain



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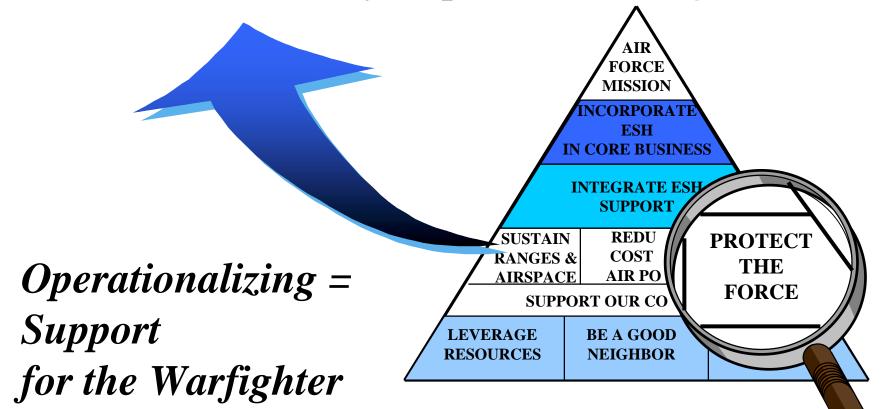


Environment, Safety and

Occupational Health

Committee

1999: The Year of "Operationalizing" ESOH



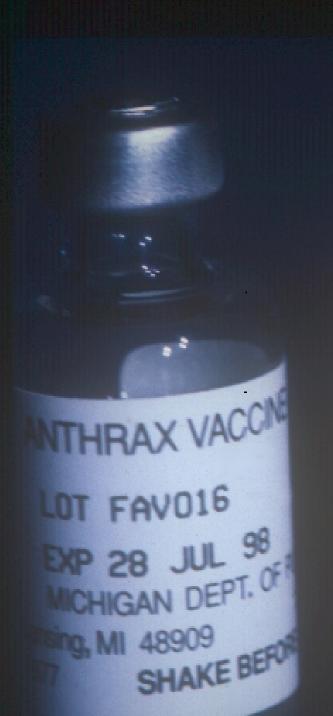


Force Health Protection

Anthrax Vaccine Implementation Program

Briefing for the Air Force Environment, Safety, and Occupational Health Committee

Colonel Harvey Crowder, AFMOA/SGOP Lieutenant Colonel Marcia Rossi, SAF/PAZ



ANTHRAX VACCINE ADSO

Preserved with benzethonium chloride 0.0025 Contains one 5mL bottle Dose 0. For Subcutaneous Use

SHAKE BEFORE USIN



Overview

- ◆ Purpose
- ◆ Problem
- ◆ Background
- **◆** Implementation
- **♦** Threat
- ◆ Vaccine
- **♦** Issues
- **♦** Solutions



Purpose

- ◆ Update ESOHC on activities of the Anthrax Vaccine Implementation Program (AVIP) & the VCSAF Anthrax IPT
- ◆ Obtain ESOHC endorsement to use MAJCOM and base-level ESOHC/EPC to enhance communication and commander involvement in support of the Anthrax Vaccine Implementation Program



Problems

- ◆ Direct leadership involvement
- ◆ Effective education
- ◆ Program monitoring



Background

- ◆ 15 December 1997, SECDEF approved the Total Force anthrax vaccination program.
 - ◆ Supplemental testing
 - ◆ Implementation and education plan
 - ◆ Immunization Tracking
 - ◆ Independent Review
- ◆ Army as Executive Agency
- ◆ Three-phased Program



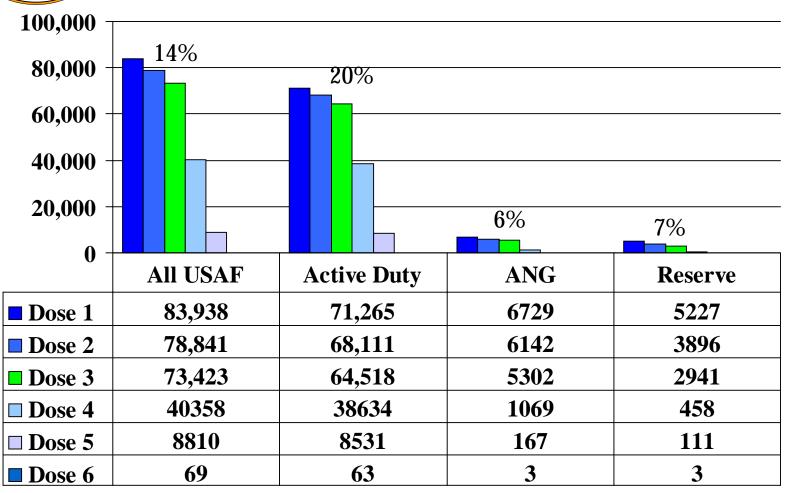
Implementation

- ◆ Phase I. Forces in rotating to high threat areas
- ◆ Phase II. Deploying forces
- ◆ Phase III. Total force and sustainment

	FY98	FY99	FY00	FY01	FY02	FY03	FY04	FY05	FY06
PHASE I	200K D	DD PERS ANNU	JALLY						
PHASE II					DOD PERS	ANNUALLY			
PHASE III						2.	6M DOD PERS	ANNUALLY	
I HASE III						_			

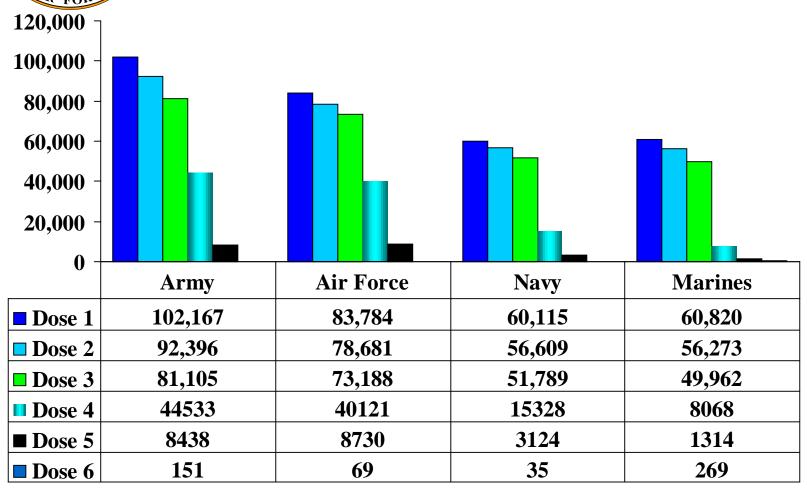


USAF Immunizations





Service Immunizations





Anthrax

- ◆ Disease
 - ◆ Worldwide in grazing animals
 - ◆ In Humans, 3 Forms
 - ♦ Skin
 - **◆** Intestinal
 - **◆** Inhalation



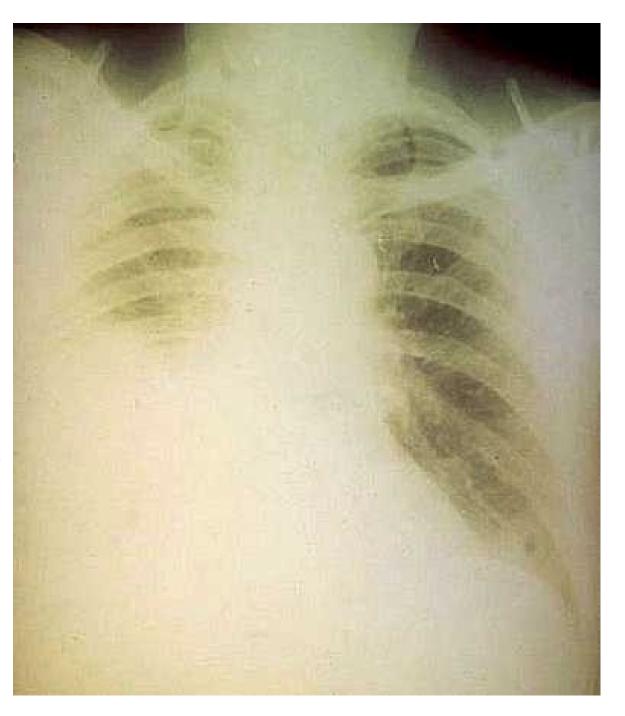
Cutaneous Anthrax Necrotic Ulcerations





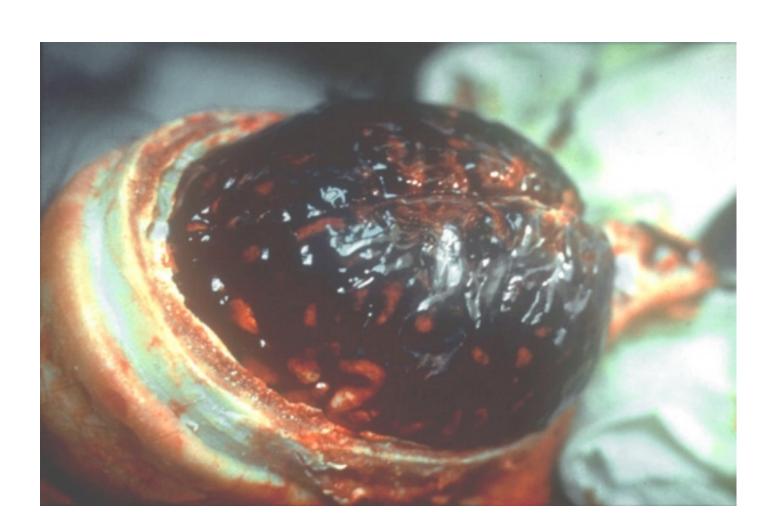
Inhalation Anthrax (Sverdlovsk)

Hemmorrhagic
Necrotizing
Mediastinitis
and Pneumonitis





Anthrax (Sverdlovsk) Hemmorrhagic Meningitis





Threat

- ◆ 10 Countries have weaponized
- ◆ Good Biological Warfare Agent
 - ◆ Easy and cheap to manufacture
 - ◆ Very stable
 - ◆ Easy to spread



Vaccine

- **♦** Safety
 - ◆ Food & Drug Administration licensure 1970
 - ◆ Adverse Effect Reporting System (VAERS)
- **♦** Effectiveness
 - ◆ Human licensure studies
 - ◆ Animal studies
- **♦** Side-effects
 - ◆ Short-term
 - ◆ Long-term



Anthrax IPT Charter

- ◆ Examine Anthrax Vaccination Immunization Program (AVIP)
 - ◆ To identify audiences we need to reach & how to reach them
 - ◆ To improve education/training
 - ◆ To review "everything"
 - Policies, processes, operations, morale, discipline
- ◆ Members of IPT represent

AF/SG AF/DP AF/JA AF/X0 AF/IL AF/RE ANG SAF/MI SAF/LL SAF/PA



Total Force Issues

- ◆ Education process differs for reserve components
 - ◆ Scheduling is a significant challenge for the Reserve component
 - ◆ Lack of active duty information infrastructure
- ◆ Concerns upon impact on civilian employment
- ◆ Refusal consequences differ from active duty



Education Issues

- ◆ Internet Web Sites : DoD's <u>www.anthrax.osd.mil</u>, as well as AF/ANG
 - ◆ Alternative (negative) sites
 - ◆ Briefings (DoD) for commanders, medical providers, airmen
 - ◆ Current education approach at installations
- ◆ AF News Service articles, AF TV/radio pieces, AF Policy Letter
- ◆ Individual counseling



Issues of Concern or Under Review

- ◆ Internet's misinformation and nonscientific journalism
- ◆ Airline pilot/employer "concerns"
- ◆ Bioport's shutdown and "bad batch"/squalene issues
- "Legitimacy" of blood for transfusions
- ◆ Long-term effects



Issues of Concern or Under Review (Continued)

- ◆ Training for commanders/flight surgeons/base public affairs officers
- ◆ Vaccine availability
- ◆ Handling of "pockets" of concern
 - ◆ Dover/McChord/ Battle Creek, MI



IPT's Assessment

◆ Educate and inform

- ◆ Use Internet, videos, brochures, commanders' calls, & medical practitioners
- ◆ Identify experts, including non-DoD, to discuss safety
 - ◆ Adverse reaction for Air Force at .011%
- ◆ Prepare commanders, medical officials and others
 - ◆ Leaders' Briefing to field
- ◆ More proactive involvement by DoD/PA and the Army
- ◆ Need to develop information warfare approach
- ◆ Engage via ESOHC/EPC-AFOSH Council



IPT's Actions

- ◆ Training initiatives Leaders' Briefing & contact with AU
- ◆ Disseminating educational materials -AFNEWS Dover video & update Internet site Searched for
- ◆ Contacted non-DoD experts CDC, Federal Aviation and Airline Pilots Associations
- ◆ Traveling briefing team
- ◆ Clarified policy: message from CSAF and letter from SAF/MI reinforce mil/civ policy



- **◆** ESOHC endorse these actions:
 - ◆ Co-chairs sign memo to MAJCOM/CVs calling for ESOHC/EPC-AFOSH Council meeting on AVIP
 - ♦ HQ USAF ESOHC distribute ESOHC minutes, Leader's Brief, AF News video, and Web sites as source data/training tools
 - ◆ MAJCOMs and installations implement AVIP leader's training program

Anthrax Vaccine Implementation Program Questions/Answers

Q1. Why are service members getting this vaccine?

A1. Anthrax is a known lethal weapon in the arsenal of at least 10 countries, many of which are hostile to the United States. Anthrax is an inexpensive weapon that could be used against deployed personnel. Vaccination before exposure is a critical part of the protection against this weapon.

Q2. What is anthrax?

A2. Anthrax is an infectious disease that normally afflicts animals, especially cattle and sheep. Anthrax spores can be produced in a dry form which may be easily turned into an aerosol weapon. When inhaled by unprotected humans, inhalation anthrax will cause respiratory failure and death as soon as a week following exposure.

Q3. Is the vaccine all that is needed to protect against inhalation anthrax?

A3. Being fully vaccinated greatly increases the chances of surviving an exposure to anthrax. Chances are further improved by other measures, especially the proper use of the protective masks.

Q4. Is this an experimental vaccine?

A4. No, the anthrax vaccine has been approved by the FDA since 1970. Michigan Biologic Products Institute (now the Bioport Corporation) licensed the vaccine (No. 99) and is the only manufacturer.

Q5. Is this vaccine safe?

A5. Yes. This vaccine has been safely administered in the U.S. to those in at-risk occupations, such as veterinarians, laboratory workers, and livestock handlers since 1970. No reports of serious adverse effects have been reported in almost three decades of use.

O6. Is there anyone who should not receive the vaccine?

A6. The anthrax vaccine should be administered only to healthy men and women from 18 to 65 years of age because investigations to date have been conducted exclusively in that population.

Q7. What about pregnancy?

A7. Anthrax vaccine, like other vaccines in the U.S., is classified as "Pregnancy Category C," which means that animal reproduction studies have not been conducted with anthrax vaccine. Therefore, prudent medical practice dictates that all vaccinations, including anthrax, should be routinely deferred during pregnancy unless clearly needed.

Q8. What other medical conditions could affect the use of this vaccine?

A8. If a person has an active infection/illness or is taking some prescription medications, a decision to give the vaccine will be made on a case by case basis.

Q9. The anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

A9. No. Several national scientific groups, including the National Academy of Sciences, have addressed this issue and have found no evidence to link the anthrax vaccine with illnesses among Gulf War veterans.

Q10. Does the vaccine cause sterility?

A10. No. The vaccination has been routinely used for almost 30 years and has not been associated with sterility. Although scientists cannot conduct experiments with lethal agents on the human reproductive system (for ethical reasons), after three decades there is ample evidence that it does not cause any harm or sterility.

Q11. What are the side effects?

A11. As with other vaccinations, pain may occur at the site of injection. Temporary side effects (redness, swelling or a small nodule at the injection site; general malaise) may occur.

Q12. Is there any proof that the vaccine is effective against inhaled anthrax?

A12.Several studies performed at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) demonstrated the excellent efficacy of the vaccine in monkeys, who most closely resemble human anthrax infection.

Q13. Could some nation manipulate anthrax to defeat our vaccine?

A13. We believe it would be difficult to develop and weaponize a form of anthrax to defeat our vaccine. The vaccine is effective against naturally occurring strains of anthrax and protection is based on a protein found in all known strains of the organism. It would be a formidable task to alter this protein, which is central to the mechanism of the disease, and still retain the effectiveness of the organism as a weapon.

Q14. Will military members be asked to sign a consent form before being given the vaccine?

A14. The vaccine is fully licensed by the FDA and does not require signed consent.

Q15. Is the anthrax vaccination program a result of lessons we learned from the 1991 Gulf War?

A15. The current world threat environment and the unpredictable nature of terrorism make it prudent to include biological warfare defense in all of our force protection planning. The greatest biological threat agent is anthrax, as validated by the Chairman of the Joint Chiefs of Staff.

Q16. In overseas areas where military family members are present, will family members be vaccinated also?

A16. Military family members will generally not be vaccinated. If the threat warrants, the first option is to withdraw them from the area.

Q17. Will service members have a choice in receiving the anthrax vaccine?

A17. No. This series of immunizations will be treated the same as other required vaccinations. All service members will be required to take the vaccinations, unless medically deferred.

Q18. Is anthrax vaccine available to the civilian population?

A18. Small quantities are made available as needed to civilians who are exposed to anthrax hazards in their work environment such as laboratory workers, researchers, and others.

Q19. How real is the threat?

A19. The current world threat environment and the unpredictable nature of terrorism make it prudent to include biological warfare defense as part of our force protection planning. The fact is that our potential adversaries have not been forthright in adhering to the 1972 Biological and Toxic Weapons Convention. Since the treaty was endorsed by international community, the number of countries developing offensive biological warfare capability has doubled. We discovered during the Gulf war that Saddam Hussein maintained an anthrax arsenal sufficient to kill every man, woman and child on the face of the earth. By 1992, we learned that the former Soviet Union maintained capability that dwarfed Iraq's by comparison. Many terrorist groups are vocal about their contemplated use of germ warfare The anthrax vaccination immunization program is the most effective method of countering the threat.

Q20. What happens to those who refuse the shots?

A20. Refusals are dealt with on a case-by-case basis, to allow commanders the flexibility to deal with each individual's specific concerns. Commanders have the full range of disciplinary options available to them just as they do for anyone who disobeys a lawful order. This ranges from personnel actions to punitive actions. It includes administrative actions such as oral and/or written counseling and reprimands, administrative discharges, Articles 15, and court-martial.

Q21. Does this policy apply to members of the Guard and Reserve as well?

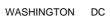
A21. A program to vaccinate all Guard and Reserve members has been developed in accordance with the Air Force Anthrax Vaccination Immunization Program, and immunization has taken place for some time. AFRC and ANG commanders are responsible

for anthrax immunization implementation. Those personnel first to receive the vaccinations were those entering high-risk theaters, regardless of length of stay.

Q22. What is squalene and is it added to the anthrax vaccine?

A22. Squalene is a natural, non-toxic substance found in plants, animals and humans. It is manufactured in the livers of humans and is a precursor to cholesterol. It is also found in foods like olive oil and eggs, in cosmetics and in over-the-counter medications. Media reports of squalene being added to the anthrax vaccine are false. There is not--and never has been--squalene in the anthrax immunization.

DEPARTMENT OF AIR FORCE





29 June 1999

MEMORANDUM FOR AF/DP

FROM: SAF/MI

SUBJECT: Anthrax Vaccine Immunization Program (AVIP)

Protecting the health of our workforce is a primary objective of the Air Force. This objective is accomplished through programs that encourage good nutrition, adequate exercise, and healthy lifestyles. Other means of protecting our people, especially for those who are assigned to or deploy to OCONUS areas, include immunizations against harmful bacteria and viruses.

In May 1998, Secretary of Defense Cohen directed that all U.S. military personnel and Department of Defense (DoD) emergency essential (E-E) civilian personnel will be immunized against anthrax. Civilian E-E positions are those located overseas or that would be transferred overseas during a crisis situation, or which require the incumbent to perform temporary duty assignments overseas during a crisis in support of a military operation. Policy governing DoD's immunization program for biological agents is reflected in DoD Directive 6205.3, dated November 26, 1993. This policy is implemented in AFJI 48-110; paragraph 20 of the AFJI states, "Federal civilian employees and other groups having status equivalent to deployable forces serving under the auspices of the Military Services are subject to the same immunization requirements as active duty personnel."

Initially, U.S. military personnel and E-E personnel were to receive the anthrax vaccine only if they were to be deployed to a high-threat area for more than 30 days. The memorandum dated 30 Mar 99 from the USD(P&R) changed this requirement. Any U.S. military personnel and E-E civilian employees assigned, deployed, or on temporary duty to high-threat areas for any period of time must initiate the vaccination series prior to entry into a high-threat area. This is a change to the original anthrax immunization policy.

WC must ensure that all personnel are aware of the requirement to receive the anthrax vaccine. I believe the anthrax vaccine offers Air Force members and E-E employees viral protection against a very real threat. The Air Force Surgeon General has implemented an anthrax immunization program that incorporates the Federal Drug administration's guidelines. All vaccine i's tested for potency and purity before shipment.

For employees who want more information concerning the vaccine. [recommend the new AVIP website, www.anthrax.osd.mil This site has been developed by the AVIP Director to provide reliable information about the disease, the vaccine and its history. I have included a

copy of the Leader's Brief, which also contains helpful information about the program. This is the briefing that is being sent to all commanders to assist them in educating their people.

My point of contact in SAF/MIM for civilian personnel policy is Ms. Charlene Bradley, 614-4752. Ms. Carol J. Thompson, 693-9764, is the point of contact for health care policy..

RUBY B. DÉMESME

Assistant Secretary of the Air Force

(Manpower, Reserve Affairs, Installations Environment)

Attachments:

- 1. USD(P&R) memo dtd 30 Mar 99
- 2. Leader's Brief

cc:

SAF/OS

AF/CV

AF/SG



DEPARTMENT OF THE AIR FORCE OFFICE OF THE CHIEF OF STAFF WASHINGTON, DC

1 4 JUN 1999

MEMORANDUM FOR ALMAJCOM- FOA/CC

FROM: **HQ USAF/CC**

1670 Air Force Pentagon Washington DC 21330-1670

SUBJECT: Anthrax Vaccination Immunization Program

Providing the best protection for our people is the highest priority. Recognizing this obligation, the Secretary of Defense approved the implementation of the Anthrax Vaccination Immunization Program. For Air Force people, I believe that immunizing them against anthrax ensures our ability to perform the expeditionary aerospace force mission. The threat of anthrax is too lethal, the loss of life is too real, and the risk of mission failure is too high for us to do anything other than give our airmen the best protection available. The initial phases of the program have been very successful. In the next few months, the program will be expanded to further protect active duty, reserve and guard personnel, as well as emergency essential civilians.

Unfortunately, inaccurate and misleading information about the anthrax vaccine has appeared on the Internet and in the media. While I am confident the anthrax vaccine is safe, effective and necessary for force protection, I also understand how misinformation may cause some members to initially question use of the vaccine. Therefore, it is imperative that we continue to make the best most accurate information available to all our personnel.

I expect personnel in the medical, legal public affairs and personnel communities to help commanders and supervisors reassure. Air Force personnel that anthrax shots are both safe and necessary. Military personnel expressing reservations after counseling should be referred to an area defense counsel to make certain they understanding the potential consequences of refusal. Only after all reasonable attempts at education and counseling have been exhausted, should other means of enforcement be considered.

MICHAEL E. RYAN General, USAF

Chief of Staff

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HQ USAF WASHINGTON DC//CV//

ALMAJCOM//CC//

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SUBJ: COMMANDER'S INVOLVEMENT IN ANTHRAX VACCINATION PROGRAM

- 1. ANTHRAX IS A MORTAL ENEMY THAT OUR AIRMEN MUST BE PREPARED TO CONFRONT AND CONQUER. THIS THREAT EXISTS AROUND THE WORLD IN AREAS OUR EXPEDITIONARY FORCES DEPLOY TO EVERY DAY. WE WILL NOT BE ABLE TO DETECT THIS ADVERSARY IN ADVANCE, DESPITE OUR BEST TECHNOLOGY. WHEN FACED BY ANTHRAK, ALL OF US MUST BE PREPARED OR MANY OF US WILL DIE.
- 2. THREAT FROM BIOLOGICAL WARFARE AGENTS IS, OF GREAT CONCERN TO THE IMENT OF DEFENSE AND TO OUR NATION. THE FORMER DIRECTOR OF THE CENTRAL: INTELLIGENCE AGENCY REFERRED TO ANTHRAX AS "THE SINGLE MOST DANGEROUS THREAT TO OUR NATIONAL SECURITY IN THE FORESEEABLE FUTURE." WE KNOW IRAQ HAD THE CAPABILITY TO DELIVER ANTHRAK DURING THE GULF WAR. WE ALSO LEARNED, IN THE POST-COLD WAR ERA, THE USSR ANTHRAK PRODUCTION PROVIDED ENOUGH AGENT TO KILL EVERY PERSON ON THE EARTH -SEVERAL TIMES OVER.
- 3. IT IS IMPERATIVE WE MAINTAIN A FIT FIGHTING FORCE READY TO CARRY

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OUT OPERATIONAL REQUIREMENTS. THE SECRETARY OF DEFENSE APPROVED IMPLEMENTATION OF THE MANDATORY ANTHRAX VACCINATION PROGRAM IN DECEMBER 1997. AFTER MUCH REVIEW BY MEDICAL AND SCIENTIFIC EXPERTS, THE SECRETARY WAS CONVINCED ANTHRAX VACCINATION WAS SAFE AND NECESSARY. WE MUST IMMUNIZE AGAINST ANTHRAX OR WE WILL SUFFER UNCONSCIONABLE COMBAT LOSSES AND FAILED MISSIONS. IMMUNIZATION IS A COMMANDER'S PROGRAM TO ENSURE THE HEALTH AND SAFETY OF OUR TROOPS.

- 4. HOWEVER, MISINFORMATION AND RUMOR HAVE UNNECESSARILY RAISED CONCERNS ABOUT THE SAFETY OF THE VACCINE WE ARE ADMINISTERING TO OUR SERVICE MEMBERS. THE MOST RECENT ACCUSATION IS THAT CERTAIN LOTS OF ANTHRAK VACCINE CONTAIN AN ADDITIVE CALLED SQUALENE. A CIVILIAN LAL KATORY TESTED THESE VACCINE LOTS AND THE RESULTS SHOW THEY DO NOT CONTAIN SQUALENE. THE FACT IS THERE HAS NEVER BEEN SQUALENE IN THE ANTHRAK VACCINE NOR IN ANY OTHER FDA-APPROVED VACCINE.
- 5. ALLEGATIONS CONTINUE TO SURFACE ABOUT THE VACCINE'S SAFETY, MANUFACTURING PROCESS, SIDE EFFECTS AND OTHER ISSUES. THIS MISINFORMATION HAS RAISED CONCERNS AMONG SOME PEOPLE. THEREFORE, COMMANDERS AND SUPERVISORS MUST BECOME EDUCATED ON THE ISSUES AND BE

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PREPARED TO REASSURE OUR PEOPLE THE SUPPLY OF VACCINE HAS BEEN TESTED FOR PURITY AND EFFECTIVENESS AND THE MANUFACTURING PROCESS IS REGULATED BY THE FDA.

- IT IS TRUE THAT SOME PEOPLE WILL HAVE MILD SIDE EFFECTS TO THE ANTHRAX SHOTS, DATA COLLECTED BY THE FDA OVER 30 YEARS SHOWS THESE REACTIONS HAVE BEEN RELATIVELY MINOR AND SHORT TERM. THESE ARE COMMON SIDE EFFECTS EXPECTED WITH ANY VACCINATION - SUCH AS REDNESS AND SWELLING AT THE INJECTION SITE. AS OF THIS DATE, THE DEPARTMENT OF DEFENSE HAS GIVEN ALMOST 839,000 DOSES OF ANTHRAK VACCINE TO MORE THAN 276,000 SERVICE MEMBERS WITH LESS THAN 60 REACTIONS REPORTED TO FDA--THAT'S A .007 PERCENT COMPLICATION RATE. NONE OF THE
- .IDUALS WITH COMPLICATIONS HAVE SHOWN LONG-TERM EFFECTS. .::
- ACCORDING TO GENERAL ROADMAN, THIS IS VERY LOW, ESPECIALLY WHEN COMPARED TO MUMPS, MEASLES, RUBELLA, DIPHTHERIA, PERTUSSIS AND TYPHOID. ABOUT 30 PERCENT OF THOSE INDIVIDUALS VACCINATED WITH ANTHRAX MAY HAVE SOME REDNESS OR SWELL AT THE SITE OF INJECTION OR MAY DEVELOP A NODULE AT THE INJECTION SITE. HISTORICALLY ABOUT 4% OF PEOPLE IMMUNIZED HAVE SYSTEMATIC REACTIONS INCLUDING FEVER AND MUSCLE

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AND JOINT ACHES AND LESS THAN 1% WILL HAVE A MORE SEVERE REACTION .. YOU CAN COMPARE THAT WITH THE TYPHOID VACCINE WHERE UP TO 98% OF PEOPLE DEVELOP TENDERNESS AT THE INJECTION SITE, 40% WITH PAIN AND 25 % WITH MALAISE. WITH THE DIPTHERIA VACCINE WE USE IX OUR CHILDREN, APPROXIMATELY 30% WILL DEVELOP SOME REDNESS AND SWELLING AT THE INJECTION SITE WITHIN 72 HOURS OF INJECTION. AS YOU CAN SEE, THE ANTHRAX VACCINATIONS COMPARE FAVORABLY WITH THESE COMMONLY USED VACCINES.

- 8. COUNTERING MISINFORMATION ABOUT THE ANTHRAX VACCINE IS ESSENTIAL. THEREFORE, AIR FORCE LEADERS MUST BECOME EDUCATED ON THE THREAT TIGING OUR PEOPLE AND THE ABSOLUTE NECESSITY OF THIS SAFE, HIGHLY L. CTIVE VACCINATION PROGRAM. AIRMEN MUST UNDERSTAND THERE IS MCTHING TO FEAR IN THE ANTHRAK VACCINE AND THIS IMMUNIZATION MAY SAVE THEIR LIVES. THOSE WITH QUESTIONS OR CONCERNS SHOULD CONTACT THEIR OWN HEALTH CARE PROVIDERS WITH QUESTIONS AND EXERCISE CAUTION WHEN RESEARCHING INFORMATION ON THE INTERNET OR RECEIVING E-MAIL THAT MAY NOT CONTAIN ACCURATE INFORMATION.
- 9. POC IS COLONEL HARVEY CROWDER, CHIEF OF PUBLIC HEALTH, AF MEDICAL

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OPERATIONS AGENCY, DSN 297-4280 OR COMM (202) 767-4280.

10. LISTED BELOW ARE RESOURCES FOR LEARNING MORE ABOUT ANTHRAX. THE DEPARTMENT OF DEFENSE AND THE AIR FORCE WEB SITES PROVIDE BRIEFING MATERIALS AND BROCHURES ABOUT ANTHRAX IMMUNIZATION AS EDUCATIONAL TOOLS FOR COMMANDERS AND SUPERVISORS.

LIST OF WEB SITES AND SOURCES OF INFORMATION:

DEPARTMENT OF DEFENSE

HTTP://WWW.DEFENSELINK.MIL/SPECIALS/ANTHRAX/

AIR FORCE

HTTP://WWW.AF.MIL/CURRENT/ANTHRAX/

TRS FOR DISEASE CONTROL

WWW.CDC,GOV

FCOD AND DRUG ADMINISTRATION

WWW.FDA.GOV/NCIDOD/DBMD/ANTHRAK.HTM

JOHNS HOPKINS

HTTP://WWW.HOPKINS-BIODEFENSE.ORG/

MAYO CLINIC

HTTP://WWW.MAYOHEALTH.ORG/MAYO/9802/HTM/ANTHRAX.HTM

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NATIONAL INSTITUTES OF HEALTH ("UNDERSTANDING VACCINES")

HTTP://WWW.NIH.GOV/

AMERICAN MEDICAL ASSOCIATEION

HTTP://WWW.AMA-ASSN.ORG/

WORLD HEALTH ORGANIZATION

HTTP://WWW.WHO.ORG/

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SUBJECT: ANTHRAX IMMUNIZATION PROGRAM SUPPORT
PLEASE DISSEMINATE TO ALL COMMANDERS IN YOUR COMMAND

- THE NATURE OF AN EXPEDITIONARY FORCE REQUIRES US TO BE PREPARED AT ALL TIMES FOR ANY POTENTIAL THREAT IN ANY LOCATION. AS COMMANDERS, WE NEED TO ENSURE OUR PEOPLE ARE PROTECTED TO THE MAXIMUM EXTENT POSSIBLE. WE ALSO NEED TO ENSURE THEY UNDERSTAND THE IMPORTANCE OF THIS IMMUNIZATION. FOR THOSE WHO ARE HESITANT, COUNSELING AND EDUCATION ARE THE KEY NOT THREAT OF PUNISHMENT.
- 2. I HAVE BEGUN TAKING MY ANTHRAX IMMUNIZATIONS. IT IS SAFE AND EFFECTIVE, AND LEXPECT ALL AIR FORCE COMMANDERS, FIRST SERGEANTS, AND SENIOR ENLISTED ADVISORS TO LEAD BY EXAMPLE IN THIS FORCE PROTECTION MEASURE. THIS MEANS BEING FIRST IN LINE FOR THE IMMUNIZATION, AND FIRST TO COMMUNICATE TO PEOPLE THE NECESSITY OF THIS LIFE-SAVING MEASURE.
- 3. AS MEMBERS ROTATE HOME, THEY MUST CONTINUE ON THE APPRESCRIBED ANTHRAX SCHEDULE. FOR THOSE WHO ARE NOT SERVING IN THE PERSIAN GULF AREA. WE EXPECT TOTAL FORCE IMMUNIZATION TO BEGIN SOMETIME THIS SUMMER.
 - 4. AGAIN, I EXPECT COMMANDERS TO LEAD IN THIS EFFORT, YOUR CLOSE INVOLVEMENT IS ESSENTIAL FOR GETTING THE WORD OUT, ASSURING THE DEADLINES ARE MET, AND KEEPING THIS ISSUE ON THE FRONT EURNER.



DoD Leader's Briefing: Force Health Protection Against Anthrax



Anthrax

- Anthrax is a known biological weapon
- Inhalational anthrax is highly lethal
- Vaccination against anthrax is critical for your protection
- This is a mandatory vaccination program except for legitimate medical exemptions and deferrals
- Anthrax vaccine is safe and effective



Background on Anthrax

- Recognized as an illness for centuries
- Spores can survive in soil for decades
- Once common where livestock were raised
- Animal anthrax can be controlled through vaccination programs with an animal vaccine
- Human infection usually results from direct contact with infected animals or animal products



Threat

- Anthrax is the most likely Biological Warfare agent:
 - Easy and cheap to produce
 - Spores make anthrax an effective biological weapon
 - Can be stored for a long time
 - Can be dispersed in the air by a variety of weapons
 - Inhalational anthrax is highly lethal
 - Odorless, colorless, and difficult to detect
- Anthrax will cause widespread illness and death among unprotected exposed personnel

Anthrax Three Disease Types

- Skin (Cutaneous) Anthrax
 - 95% of natural cases; spores enter skin breaks
 - Responds well to antibiotics... 1 in 5 die if untreated
- Gastrointestinal Anthrax
 - Ingestion (e.g., eating undercooked, infected meat)
 - Severe GI symptoms... 50% may die even with treatment
- INHALATIONAL ANTHRAX
 - "Flu-like symptoms" early, rapid deterioration, and death
 - Mortality may exceed 80% after symptoms occur, <u>despite</u> treatment



Inhalational Anthrax

- Inhalational anthrax occurs when the spores enter the body through the lungs
- Not transmitted person to person
- Spores migrate to lymph system where bacteria multiply and produce lethal toxins
- Toxins cause bleeding and destruction of the brain or vital organs in the chest resulting in death



Anthrax Vaccine Facts

- Vaccine primes body's natural defense system to fight anthrax
- Anthrax vaccine cannot cause anthrax
- Critical part of your protection against anthrax
- Licensed by the Food and Drug Administration in 1970
 - Safely used for nearly 30 years
 - Supplemental tests before released to the Department of Defense (DoD)



Response to Vaccine

- Anthrax vaccine, like other vaccines, stimulates your body to produce protective antibodies
 - Everyone has some antibody response after 2 doses
 - The full series is needed to obtain maximum and on-going protection
 - Everyone gets some protection
- Even with a good antibody response, your defense system can be overwhelmed given sufficient number of spores



Pregnancy

- All vaccinations routinely deferred during pregnancy
 - Continue vaccinating when no longer pregnant
- Before vaccination, women should tell their healthcare provider if they think or know they are pregnant
- Anthrax vaccine can be safely given to women who are breast feeding
- No reason to delay pregnancy or conception efforts after vaccination

Other Health Facts

- The anthrax vaccine contains no living or dead anthrax organisms
- Pain may occur at injection site
- May experience mild, temporary side effects
- No scientific evidence that any vaccine causes cancer or infertility

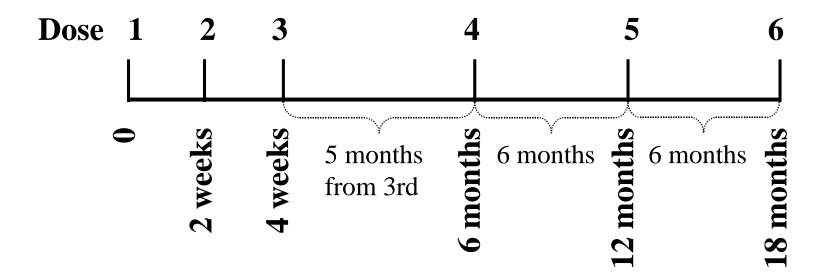


VIDEO AF/SG Speaking on Anthrax

14 Jun 1999 AFNEWS Anthrax Segment

Forwarded as Separate
Attachment to Local Public
Affairs Offices

Vaccine Schedule



• 6 shots over 18 months, then annual booster



Adverse Reactions

- Mild local reactions (30%)
 - Redness, tenderness at site for up to 24-72 hours
 - Subcutaneous nodules (lumps)
- Moderate local reactions (4%)
 - Redness/hardness > 5 cm, tenderness, itching for up to 24-72 hours
- Severe local reactions rare (<1%)
- Very rare systemic reactions occur (<0.2%)
- Extremely rare systemic reactions (e.g., Guillain Barre Syndrome) may occur with all vaccines



Adverse Event Reporting

- FDA National Vaccine Adverse Event Reporting System (VAERS)
 - FDA and DoD review 100% of adverse events reports submitted to FDA
 - Anyone can submit a Form VAERS-1
- A Form VAERS-1 submission is REQUIRED for:
 - Loss of duty > 24 hours
 - Hospitalization
 - Suspected vaccine lot contamination
- Form VAERS-1 may be obtained by calling:
 - 1-800-822-7967 or at www.fda.gov/cber/vaers.htm.



Reserve Component Adverse Event Procedures

- An individual experiencing a vaccine-associated adverse event in a non-duty status:
 - Seek medical evaluation at a DoD or civilian medical treatment facility if necessary
 - Must report the event to their unit commander or designated representative as soon as possible
- Form VAERS-1 is the same as Active Duty
- Commander will initiate Line of Duty and/or Notice of Eligibility

ANTHRA SECTION PROTECTS

Summary

- Anthrax is a known biological weapon
- Inhalational anthrax is highly lethal
- Vaccination against anthrax is critical for your protection
- This is a mandatory vaccination program
- Anthrax vaccine is safe and effective



Information Sources

- Chain of command
- Http://www.anthrax.osd.mil
- Http://www.defenselink.mil
- Http://www.cdc.gov



The following is a list of anthrax-related websites which may be referenced for further information.

Centers for Disease Control

www.cdc.gov

Food and Drug Administration

www.fda.gov

Johns Hopkins

http://www.hopkins-biodefense.org/

Mayo Clinic

http://www.mayo.edu/

National Institutes of Health ("Understanding Vaccines")

http://www.nih.gov/

American Medical Association

http://www.ama-assn.org/

World Health Organization

http://www.who.org/

Department of Defense

http://www.defenselink.mil/specials/Anthrax/

Air Force

http://www.af.mil/current/anthrax/